



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/484,704 | 01/18/2000 | Kelly J. Henrickson | 650053.91126 | 1001 |

26710 7590 07/29/2003

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE
SUITE 2040
MILWAUKEE, WI 53202-4497

| |
|----------|
| EXAMINER |
|----------|

SIEW, JEFFREY

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1637

DATE MAILED: 07/29/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|-------------------|
| Office Action Summary | Application N . | Applicant(s) |
| | 09/484,704 | HENRICKSON ET AL. |
| Examiner | Art Unit | |
| Jeffrey Siew | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 34-37 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) 34-37 is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karron et al (J. Clinical Micro vol. 32 no. 2 pp. 484-88 1994) in view of Wu et al (EP0418960 A2 March 27, 1991) in further view of Sninsky et al (US5,176,995 Jan. 5, 1993).

Karron teach PCR rapid detection of HPIV-3 of HN gene using RT-PCR (see whole doc. esp. abstract).

Karron do not teach protein linked probe nor unequal primer concentration.

Wu et al teach a method of performing polymerase chain reaction using unequal primer concentration in which primer pairs is at least 2:1 (see abstract). They teach a polymerase reaction in which denaturation is performed thirty times at 95C.

Sninsky et al teach detection by hybridizing with a probe that is complementary to conserved nucleic acid sequence to genome of virus (see col. 15 line 40-45) and using biotin labeled probes (see col. 16 line 9).

One of ordinary skill in the art would have been motivated to apply Wu et al's primer ratios to Karron's method in order to successfully amplify the virus nucleic acid. As Wu et al teach that unequal primer ratio of 2:1 would lead to successful amplification, it would have been

prima facie obvious to apply Wu et al's ratios to Karron's method in order to maximize the amplification of viral nucleic acid.

Moreover, one of ordinary skill in the art would have been motivated to apply Sninsky et al's teaching of biotin labeled probes to Karron's detection method in order to quickly detect amplified virus. As biotin label probes allow rapid colorization, it would have been prima facie obvious to apply Sninsky et al's teaching of biotin probes to the Karron's detection method in order to rapidly detect viral sequences without the use of harmful radioactivity.

REBUTTAL

3. The response filed 6/2/03 has been fully considered and deemed not persuasive. The response has amended the independent claim 34 to incorporate language "wherein the double stranded amplification product is present in a greater amount compared to product formed with equal primer concentrations". The response is reminded that the claims are method claims and examined on their active steps. The active steps in claims still read on the Wu et al. The unexpected result of better product yield from doing the same prior art steps does not obviate the prior art reference which recites the same active steps. Moreover, the recitation does not provide adequate patentable weight because the yield of the method of using equal primer concentrations involves a multitude of variables that may affect yield including cycle, temperature and reaction conditions. The rejections are maintained. It may be helpful to explore specific primer concentrations as an avenue to overcome the cited prior art.

SUMMARY

7. No claims allowed.

CONCLUSION

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.


JEFFREY SIEW
PRIMARY EXAMINER

July 25, 2003